Practitioner's Docket No. <u>U 016457-9</u>

**PATENT** 

## TRANSMITTAL LETTER TO THE U.S. DESIGNATED OFFICE (DO/US)--ENTRY INTO THE U.S. NATIONAL STAGE UNDER CHAPTER I

INTERNATIONAL AF	PLICATION NO.	INTERNATION	AL FILIN	NG DATE	PRIORITY DATE C	LAIMED
PCT/IN2005/0000	86	17 MARC	H 200	)5	18 MARCH	2004
TITLE OF INVENTIO	N					
	NOVEL	COMPOSITION	FOR	TOPICAL	DELIVERY	
APPLICANT(S)	<u> </u>			•		
1.	JAIN, R	ajesh				
2.	JINDAL,	Kour, Chand				
3.	SINGH,	Sukhjeet	ı			
4.	SIHORK	AR, Vaibhav				

Mail Stop PCT Commissioner for Patents P. O. Box 1450 Alexandria, VA 22313-1450

ATTENTION: DO/US

Optional Customer No. Bar Code



PATENT TRADEMARK OFFICE

## COMPLETION OF FILING REQUIREMENTS FOR INTERNATIONAL APPLICATION ENTERING NATIONAL STAGE IN U.S. DESIGNATED OFFICE (DO/US) UNDER 35 U.S.C. 371

(check and complete the following item, if applicable)

[x] This replies to the Notice of Missing Requirements under 35 U.S.C. § 371 and 37 C.F.R. 1.494 (FORM PCT/DO/EO/905).

[x] A copy of FORM PCT/DO/EO/905 accompanies this response.

**WARNING:** 

\*WARNING:

Where the items being submitted to complete the entry of the international application into the national phase are subsequent to 30 months from the priority date, the application is still considered to be in the international stage. If mailing procedures are utilized to obtain a date, the express mail procedure of 37 CFR 1.10 must be used (because international application papers are not covered by an ordinary certificate of mailing. 37 CFR 1.8(2)(xi).

NOTE: Documents and fees must be clearly identified as a submission to enter the national stage under 35 USC 371.

Otherwise, the submission will be considered as being made under 35 USC 111. 37 CFR 1.494(f).

## CERTIFICATION UNDER 37 C.F.R. 1.10\*

(Express Mail label number is mandatory.)
(Express Mail certification is optional.)

I hereby certify that this Completion of Filing Requirements and the papers indicated as being transmitted therewith is being deposited with the United States Postal Service on this date <u>July 9, 2007</u>, in an envelope as "Express Mail Post Office to Addressee" Mailing Label Number <u>EV 927 570 005 US</u>, addressed to the: Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

(type for print name of person mailing paper

Signature of person mailing paper

WARNING: Certificate of mailing (first class) or facsimile transmission procedures of 37 C.F.R. 1.8 cannot be used to obtain a date of mailing or transmission for this correspondence.

Each paper or fee filed by "Express Mail" must have the number of the "Express Mail" mailing label

placed thereon prior to mailing, 37 C.F.R 1.10(b).

"Since the filing of correspondence under § 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will **not** be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

(Completion of Filing Requirements for International Application Entering National Stage in Designated Office (DO/US) under 35 USC 371-page 1 of 7) 13-8

#### **DECLARATION OR OATH**

NOTE: 37 C.F.R. § 1.495(c): "If applicant complies with paragraph (b) of this section before expiration of thirty months from the priority date but omits... the oath or declaration of the inventor (35 U.S.C. 371(c)(4) and § 1.497), if a declaration of inventorship in compliance with § 1.497 has not been previously submitted in the international application under PCT Rule 4.17(iv) within the time limits provided for in PCT Rule 26ter.1, applicant will be so notified and given a period of time within which to file the ... oath or declaration in order to prevent abandonment of the application .... The payment of the surcharge set forth in § 1.492(e) is required for acceptance of the oath or declaration of the inventor later than the expiration of thirty months after the priority date."

I. (a) [x] No original declaration or oath was filed. Enclosed is the original declaration or oath for this application.

#### OR

(b) [ ] The declaration or oath that was filed was determined to be defective. A new original oath or declaration is attached.

NOTE: For surcharge fee for filing declaration after filing date, complete item IV(2).

NOTE: Acceptable minimums in the declaration in an ordinarily filed U.S. application for identification of the specification to which it applies are:

- (A) application number (consisting of the series code and the serial number, e.g., 08/123,456);
- (B) serial number and filing date;
- (C) attorney docket number which was on the specification as filed;
- (D) title which was on the specification as filed and reference to an attached specification which is both attached to the oath or declaration at the time of execution and submitted with the oath or declaration; or
- (E) title which was on the specification as filed and accompanied by a cover letter accurately identifying the application for which it was intended by either the application number (consisting of the series code and the serial number, e.g., 08/123,456), or serial number and filing date. Absent any statement(s) to the contrary, it will be presumed that the application filed in the PTO is the application which the inventor(s) executed by signing the oath or declaration.

M.P.E.P. § 602, 8th ed.

NOTE: Another minimum found acceptable in the declaration is the filing date (i.e., date of express mail) and the express mail number, useful where the serial number is not yet known. But note the practice where the express mail deposit is a Saturday, Sunday or holiday within the District of Columbia. 37 CFR 1.10(c).

NOTE: 37 CFR 1.41(a) points out that "Full names must be stated, including the family name and at least one given name without abbreviation together with any other given name or initial"

# (complete as applicable)

Attache	ed is a			
	(a)	[]	Statement by practitioner that papers attached to declarathose filed in PTO to get a filing date	tion are a copy of
	(b)	[]	Statement that substitute specification contains no new r	natter.
	(c)	[]	Preliminary Amendment	
	(d)	[]	Submission of "Sequence Listing," computer readable commendment pertaining thereto for biotechnology invention nucleotide and/or amino acid sequence	
			TRANSMITTAL OF ENGLISH TRANSLATION OF NON-ENGLISH LANGUAGE PAPERS	
NOTE:	from the if it was of time verthe processor of thirty	priority de originally f within whic essing fee s months af	O(c): "If applicant complies with paragraph (b) of this section before ate but omits a translation of the international application, as filed filed in another language (35 U.S.C. 371(c)(2)) applicant will be so the file the translation in order to prevent abandonment of the asset forth in § 1.492(f) is required for acceptance of an English translatifier the priority date A 'Sequence Listing' need not be translated Rule 12.1(d) and the description complies with PCT Rule 5.2(b)."	, into the English language, notified and given a period pplication. The payment of ion later than the expiration
II.	[]	applica	ted herewith, is a English translation of the non-English tion papers as originally filed. It is requested that this translation purposes in the PTO. (See 37 CFR 1.495)	nslation be used as the
NOTE:			ing a non-English application, and submission of an English translatio omplete item IV(3) below.	n later than 30 months after
NOTE:	A non-E 1.69(b).	inglish oai	th or declaration in the form provided or approved by the PTO need t	not be translated. 37 CFR §
III.			FEES	
NOTE:	See 37 C	CFR § 1.28	8(a).	
1.	Fees for search, exam or claims			
	[]		S. Search Report filed —\$400.00; ntity—\$200.00	\$
	[]	No Sea	rch Report —\$500.00; small entity —\$250.00	\$
	[]	Exam I	Fee not paid to U. S—\$200.00; small entity—\$100.00	\$

		ſJ	not satisfied—\$100.00; small entity—\$50.00	,	\$	
		[ ]	U. S. Search fee with U.S. WO or IPER condition satisfied—\$0.00	าร	\$	
		[]	Spec and drawing, each 50 pages over 100 37 C.F.R. 1.16(s)—\$250.00		\$	
		[]	Each independent claim in excess of 3 (37 CFR 1.492 \$200.00; Small entity—\$100.00)		\$	
		[]	Each claim in excess of 20 (37 CFR 1.492 - \$50.00; small entity—\$25.00)		\$	
		[]	Multiple dependent claim(s) (37 CFR 1.492 - \$360.00; small entity\$180.00)	)	\$	
	2.	Surcha	rge fees			
		[x ]	Surcharge set forth in § 1.492(e), for accepting the declaration later than 30 months after the priority date in filing an application in the U.S. pursuant to § 1.495(c)—\$130.00; small entity—\$65.00		\$ 130.0	<u> </u>
	NOTE:	The prod	cessing fee in the next item (Number 3) below is not subject to a	a reduction for sma	ıll entity statu	s.
	3.	[].	Processing fee set forth in § 1.492(f), for acceptant of an English translation later than 30 months after the priority date—\$130.00		\$	
07/10/2007	MKAYPAGH	00000122	10593136	Total fees	\$ <u>130.</u>	00
01 FC:1617			130.00 OP			
			SMALL ENTITY STATU	S		
	IV.	A state	ment that this filing is by a small entity			
	NOTE:	See 37 (	CFR 1.28(a). (check and complete applicable	items)		
		a.	[ ] is attached. [ ] was filed on (original). [ ] was made by paying a small-entity basic nation	onal filing fee		
	WARNI	'NG:	"Small entity status must not be established unless the per- unequivocally make the required self-certification." M.P.E (emphasis added).			

#### **EXTENSION OF TIME**

(complete (a) or (b), as applicable)

V.

NOTE: 37 C.F.R. § 1.704(b)"... an applicant shall be deemed to have failed to engage in reasonable efforts to conclude processing or examination of an application for the cumulative total of any periods of time in excess of three months that are taken to reply to any notice or action by the Office making any rejection, objection, argument, or other request, measuring such three-months period from the date the notice or action was mailed or given to the applicant, in which case the period of adjustment set forth in § 1.703 shall be reduced by the number of days, if any, beginning on the day after the date that is three months after the date of mailing or transmission of the Office communication notifying the applicant of the rejection, objection, argument, or other request and ending on the date the reply was filed. The period, or shortened statutory period, for reply that is set in the Office action or notice has no effect on the three-month period set forth in this paragraph."

The proceedings herein are for a patent application. The provisions of 37 C.F.R. § 1.1 36(a) apply.

(a) [ ] Applicant petitions for an extension of time, the fees for which are set out in 37 C.F.R. § 1.17(a)(1)-(4), for the total number of months checked out below:

	Extension (months)	Fee for other than small entity	Fee for small entity	
[]	one month	\$ 120.00	\$ 60.00	
[]	two months	\$ 450.00	\$ 225.00	
[]	three months	\$ 1,020.00	\$ 510.00	
[]	four months	\$ 1,590.00	\$ 795.00	
NOTE:	The 2-month time period for reply to A Notice to File Missing Parts of an Application is not identified on the Notice as a statutory period subject to 35 U.S.C. 133. Thus, extensions of time of up to 5 months under 37 CFR 1.136(a), followed by additional time under 37 CFR 1.136(b), when appropriate, are permitted MPEP 710.02(d)(c), $8^{th}$ ed.			
[]	five months	\$ 2,160.00	\$ 1,080.00	

If an additional extension of time is required, please consider this a petition therefore.

(check and complete the next item, if applicable)

] An extension for	months has already been secured.	The fee paid therefor of \$
is deducted from the total	fee due for the total months of ex	tension now requested.
Extension fee due with this request \$	· · · · · · · · · · · · · · · · · · ·	
		•

Fee \$

or

(b) [x] Applicant believes that no extension of term is required. However, this conditional petition is being made to provide for the possibility that applicant has inadvertently overlooked the need for a petition and fee for extension of time.

### TOTAL FEE DUE

VI. Th	e total f	fee due is:  Completion fee(s)  Extension fee (if any)	\$ <u>130.00</u> \$
		TOTAL FEE DUE	\$ 130.00
<b>3711</b>		PAYM	MENT OF FEES
VII.		[x] Enclosed is a check in the [] Charge Account No. 12-04 A duplicate of this request is a	425 in the amount of \$
VIII.		AUTHORIZATION TO	O CHARGE ADDITIONAL FEES
WARN	ING:	Accurately count claims, especially m	nultiple dependent claims, to avoid unexpected high charges.
NOTE:	requiring for extended or all red or future of the fed	g a petition for an extension of time und usion of time for the appropriate length quired extension of time fees will be trea e reply requiring a petition for an exten e set forth in § 1.17(a) will also be trea	elication that is an authorization to treat any concurrent or future reply der this paragraph for its timely submission, as incorporating a petition of time. An authorization to charge all required fees, fees under § 1.17 ated as a constructive petition for an extension of time in any concurrent ision of time under this paragraph for its timely submission. Submission ted as a constructive petition for an extension of time in any concurrent the under this paragraph for its timely submission." 37 CFR 1.136(a)(3)
NOTE:	will the p		t be returned unless specifically requested within a reasonable time, no ounts over twenty-five dollars may be returned by check or, if requested 1).
	[X]	•	authorized to charge the following additional fees that mag during the entire pendency of this application, to Accoun
	[X]	37 C.F.R. 1.492(a), (b) or (c) 37 C.F.R. 1.492 (presentation	
NOTE:	be paid, in any n	or these claims canceled by amendmen	dependent claims not paid on filing, or on later presentation, must onl nt prior to the expiration of the time period set for response by the PTC )), it might be best not to authorize the PTO to charge additional clain ments after final action.
	[X] [X] [X]	37 C.F.R. 1.17 (application pr	ges over 100 37 C.F.R. 1.16(s) rocessing fees) nsion fees pursuant to § 1.136(a).

While 37 CFR 1.17(a), (b), (c) and (d) deal with extensions of time under § 1.136(a), this authorization should be made only with the knowledge that: "Submission of the appropriate extension fee under 37 CFR 1.136(a) is to no avail unless a "quest or petition for extension is filed." (Emphasis added). Notice of

WARNING:

November 5, 1985 (1060 O.G. 27).

NOTE: Section 1.311(b) provides that an authorization to charge the issue fee (§ 1.18) to a deposit account may be filed in an individual application only after the mailing of the notice of allowance. Accordingly, general authorizations to any fees and specific authorizations to pay the issue fee that are filed prior to the mailing of a notice of allowance will generally not be treated as requesting payment of the issue fee and will not be given effect to act as a reply to the notice of allowance. Applicant, when paying the issue fee, should submit a new authorization to charge fees, such as by completing box 6b on the current PTOL 85-B form. Where no reply to the notice of allowance is received, the application will stand abandoned notwithstanding the presence of general authorizations to pay fees or a specific authorization to pay the issue fee that were submitted prior to mailing of the notice of allowance. Where an attempt is made to pay the issue fee but an incorrect amount is submitted, § 1,311(b)(1), or where the Office's issue fee transmittal form (currently PTOL-85(B)) is completed by applicant ans submitted, § 1.311 (b)(2), in reply to a notice of allowance, an exception will be made. Such submissions will operate as a request to charge the issue fee to any deposit account identified in a previously filed (i.e., submitted prior to the mailing of the notice of allowance) authorization to charge fees, and will be allowed to act as payment of the correct issue fee. § 1.311(b). See also the change to § 1.26(b), Notice of September 8, 2000, Fed. Reg. 54603-54683, at 54646 and 54647.

NOTE: 37 CFR 1.28(b) requires "Notification of any change in loss of entitlement to small entity status must be filed in the application . . . prior to paying, or at the time of paying . . . issue fee." From the wording of 37 CFR 1.28(b): (a) notification of change of status must be made even if the fee is paid as "other than a small entity" and (b) no notification is required if the change is to another small entity

[ ] 37 C.F.R. 1.492(e) and (f) (surcharge fees for filing the declaration and/or an English translation of an international application later than 30 months from the earliest claimed priority date)

**WARNING**:

It is suggested that you always check this last authorization.

[X] Refund any overpayment to deposit account 12-0425

Reg. No.: 33,778

Tel. No.: (212)708-1935

Customer No.:00140

SIGNATURE OF PRACTITIONER

JANET I. CORD

(type or print name of practitioner)

P.O. Address

c/o Ladas & Parry LLP 26 West 61<sup>st</sup> Street New York, N.Y. 10023

Customer No.:

00140

PATENT TRADEMARK OFFICE



### United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

FIRST NAMED APPLICANT U.S. APPLICATION NUMBER NO. ATTY. DOCKET NO. Rajesh Jain

10/593,136

U 016457-9

PCT/IN05/00086

I.A. FILING DATE

PRIORITY DATE

03/17/2005

04/28/2004

140 LADAS & PARRY 26 WEST 61ST STREET NEW YORK, NY 10023



**CONFIRMATION NO. 6969** 371 FORMALITIES LETTER

INTERNATIONAL APPLICATION NO.

\*OC000000024211209\*

Date Mailed: 06/05/2007

## NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Copy of the International Application filed on 09/18/2006
- Copy of the International Search Report filed on 09/18/2006
- Copy of IPE Report filed on 09/18/2006
- Preliminary Amendments filed on 09/18/2006
- Information Disclosure Statements filed on 09/18/2006
- Request for Immediate Examination filed on 09/18/2006
- U.S. Basic National Fees filed on 09/18/2006
- Priority Documents filed on 09/18/2006
- Power of Attorney filed on 09/18/2006
- Specification filed on 09/18/2006
- Claims filed on 09/18/2006
- Abstracts filed on 09/18/2006
- Drawings filed on 09/18/2006

The following items MUST be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date.

ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

The time period set above may be extended by filing a petition and fee for extension of time under the provisions

of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web. <a href="https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html">https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html</a>

For more information about EFS-Web please call the USPTO Electronic Business Center at **1-866-217-9197** or visit our website at <a href="http://www.uspto.gov/ebc.">http://www.uspto.gov/ebc.</a>

If you are not using EFS-Web to submit your reply, you must include a copy of this notice.

DEBORAH D WILLIAMS

Telephone: (703) 308-9140 EXT 205

### PART 1 - ATTORNEY/APPLICANT COPY

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/593,136	PCT/IN05/00086	U 016457-9

FORM PCT/DO/EO/905 (371 Formalities Notice)